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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,017	12/12/2005	Maria Cristina Geroni	18086	9303

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SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/533,017	**Applicant(s)** GERONI ET AL.	
	Examiner MEGHAN FINN	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3,5,7 and 11-14*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

Meghan Finn
Examiner
Art Unit: 1614

Continuation of 3. NOTE: The amendment filed April 04, 2008 will not be entered into the record because the amendments to claims 1, 3, 5, and 7 raise new issues which would require further consideration and search.
In particular, applicant has amended the claims such that the patient is suffering from liver cancer or liver metastases, which is a significant limitation compared to the previous claim in which the patient was merely in need of a drug metabolized by CYP3A and as such it would require a new search, new considerations of the prior art, and new considerations under 112 first paragraph.
Accordingly, the proposed after-final amendment filed on April 04, 2008 will not be entered into the record because it raises new issues that require further consideration and/or search as noted supra, and therefore does not materially reduce or simplify the issues for appeal.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's request for reconsideration of the present application with regards to the rejections under 35 U.S.C. 103, in light of the amendments made to the claims proposed and presented in the after-final amendment has been made. In light of the fact that the propsed amendments to the claims will not be entered into the record, and further in view of the fact that the accompanying remarks are soley directed to the obviation of this rejection of the propsed amendments, the remarks are not found to be persuasive.
For completeness of the record, Applicant's remarks regarding the lack of teaching in the cited references of Collins et al., and Beulz-Riche et al. has been fully considered, but again are not found to be persuasive. In view of the fact that the proposed amendment to the claims will not be entered into the record for the reasons discussed above, the claims are, therefore, limited in such a manner as to include patients in need of a drug metablized by CYP3A, and not limited to liver cancer.
Applicant argues that the two teachings of Collins et al. and Beulz-Riche et al. do not make obvious the amended claims as they are propsed to be entered into the application, and applicant makes no attempt to argue that they do not make obvious the previous claim set, as rejected in the final rejection on December 05, 2007, involving a patient in need of a drug which is metabolized by CYP3A. Applicant also argues that the Collin's et al. reference teaches ascertaining CYP3A levels in order to eliminate patients for whom treatment with docetaxel should be avoided, however it would have been obvious to one of ordinary skill in the art at the time of the invention that this system could also be used to identify those with which the treatment would be most effective, as the meausring indication will indicate either way, depending on the patient, and in both cases, the technology of measuring CYP3A levels is used to optimize treatment which is the same goal.

In absence of any additional arguments or remarks regarding the patentability of the claims pending at the time of the final rejection, the claim amendments will not be entered and the claims remain rejected for the reasons of record previously set forth in the final rejection of December 05, 2007.